APR 15 2013

5.1 Submitter's Name, Address, Telephone Number, Contact Person, and Date Summary Prepared

A.	Company Name:	Aaren Scientific Inc.
B.	Company Address:	4290 E. Brickell St., Bldg. A Ontario, CA 91761
C.	Company Phone:	1 (909) 937-1033
D.	Contact Person:	Robert K. Sheehan Vice President, Regulatory Affairs and Quality Systems Aaren Scientific Inc. 4290 East Brickell St., Bldg. A Ontario, CA 91761 USA Phone +1 (909) 937-1033 ext. 108 Email: rksheehan@aareninc.com

5.2 Date Summary Prepared

January 5, 2013

5.3 Name of Device, Including Trade Name and Classification Name

A.	Device Trade Name:	Aero Z Cartridge IOL Delivery System
B.	Common Name:	Small Incision Injector
C.	Classification Name(s):	Intraocular lens guide
D.	Classification Regulation:	21 CFR 886.4300 Class I
E.	Product Code:	MSS
F.	Advisory Panel:	Ophthalmic

5.4 Predicate Devices

The Aero Z Cartridge IOL Delivery System is substantially equivalent to the Monarch III IOL Delivery System (C Cartridge) device cleared under 510(k) K112977 with respect to indications for use, materials and mechanism of action.

5.5 Device Description

The Aero Z Cartridge IOL Delivery System is a two-part device comprised of a reusable handpiece and single use disposable cartridge. The single use disposable cartridge is fabricated from polypropylene with a glyceryl monostearate (GMS) agent incorporated for lubricity. It is intended for single use only and is provided sterile. The reusable handpiece is titanium, is supplied non-sterile and is designed to accommodate the cartridge and lens for delivery of the lens into the eye. The reusable handpiece is supplied in both a push-and-turn and screw type configuration.

5.6 Indications for Use

The Aero Z Cartridge IOL Delivery System is indicated to fold and insert Aaren Scientific IOLs that have the use of this inserter in their approved labeling.

5.7 Comparison of Technological Characteristics

The Aero Z Cartridge IOL Delivery System has the same indications for use, materials and mechanism of action as the predicate device (Alcon Research Monarch III IOL Delivery System, C Cartridge) device.

Table 5.1: Comparison of Z Cartridge IOL Delivery System with Predicate Device

Device Name	Aaren Scientific Z Cartridge IOL Delivery System	Alcon Research Monarch® III IOL Delivery System (C Cartridge)
510(k) Number	**K123888**	**K112977**
Substantial Equivalence Characteristics		
Intended Use	The Z Cartridge IOL Delivery System is indicated to fold and insert Aaren Scientific Models EC-3 and EC-3 PAL intraocular lenses into the posterior chamber of the eye	Folding and injection of AcrySof® intraocular lenses into the posterior chamber of the eye
Anatomical Site of Use	Posterior chamber of the eye	Posterior chamber of the eye
Components	Reusable handpiece and single-use, sterile Cartridge	Reusable handpiece and single-use, sterile Cartridge
Handpiece		
Material	Titanium alloy	Titanium alloy
Lens Injecting Mechanism	Syringe-like (Push style) and Push-and-turn rotational (Screw style)	Push and turn
Configuration	Barrel and plunger assembly, the barrel has a chamber to accept the Cartridge and the plunger advances the lens for injection	Barrel and plunger assembly, the barrel has a chamber to accept the Cartridge and the plunger advances the lens for injection
Sterilization	Flash autoclave or steam sterilization by user	Flash autoclave or steam sterilization by user
Cartridge		
Material	Polypropylene with a glycerol monostearate (GMS) lubricity agent	Polypropylene with a polyvinylpyrolidione (PVP) coating on the inner lumen
Loading Chamber	Lumen with wings for folding	Internal Cartridge geometry
Configuration	Lens loading and folding area connected to a lens injecting nozzle	Lens loading and folding area connected to a lens injecting nozzle
Sterilization	Ethylene oxide (EtO)	Ethylene oxide (EtO)

5.8 Brief Summary of Nonclinical Tests and Results

In accordance with ISO 10993-1:2009, cytotoxicity, sensitization and irritation testing were performed on the IOL Delivery System. The device was found to be non-cytotoxic, non-sensitizing, and non-irritating. Testing conducted in accordance with ISO 11979-3 demonstrated that the Aero Z Cartridge IOL Delivery System can deliver IOL Models EC-3 and EC-3 PAL without significantly impacting the optical or mechanical performance, dimensions or the cosmetic appearance of the lens.

Based on the indications for use and the technological characteristics, it can be concluded that the Aero Z Cartridge IOL Delivery System is substantially equivalent to the predicate device.

5.8 Substantial Equivalence

On the basis of the same indications for use, materials and mechanism of action, the Aero Z Cartridge IOL Delivery System is substantially equivalent to the predicate device (Monarch III IOL Delivery System, C Cartridge).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 15, 2013

Aaren Scientific, Inc.
% Mr. Robert Sheehan
Vice President of Regulatory Affairs
and Quality Systems
4290 East Brickell Street, Bldg A
Ontario, CA 91761-1569

Re: K123888
Trade/Device Name: AERO™ Z Cartridge IOL Delivery System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I (reserved)
Product Code: MSS
Dated: March 7, 2013
Received: March 11, 2013

Dear Mr. Sheehan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: Aero Z Cartridge IOL Delivery System

Indications for Use:

The Aero Z Cartridge IOL Delivery System is indicated to fold and insert Aaren Scientific IOLs that have the use of this inserter in their approved labeling.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tieuvi H Nguyen
2013.04.05 15:55:07 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number: K123888